

1 **LOS ANGELES COUNTY PHARMACEUTICALS AND SHARPS**

2 **COLLECTION AND DISPOSAL STEWARDSHIP ORDINANCE**

3 An ordinance amending Title 11 – Health and Safety of the Los Angeles County Code,
4 relating to requirements for the collection and disposal of unwanted drugs and sharps.

5 The Board of Supervisors of the County of Los Angeles ordains as follows:

6 Chapter 11.__ is hereby added as follows:

7 **Chapter 11.__ – Stewardship Program for Collection and Disposal of Unwanted**

8 **Covered Drugs and Unwanted Sharps.**

9 11.__.010 Title.

10 11.__.015 Purpose

11 11.__.020 Definitions.

12 11.__.030 Stewardship Plans – Participation.

13 11.__.040 Stewardship Plans – Components.

14 11.__.050 Stewardship Plans – Collection of Covered Drugs and Sharps.

15 11.__.060 Stewardship Plans – Disposal of Covered Drugs and Sharps.

16 11.__.070 Stewardship Plans – Administrative and Operational Costs.

17 11.__.080 Stewardship Plans – Reporting Requirements.

18 11.__.090 Stewardship Plans – Identification of Responsible Stewards of Covered
19 Drugs and Sharps.

20 11.__.100 Stewardship Plans – Review of Proposed Plans.

21 11.__.110 Stewardship Plans – Prior Approval for Change.

22 11.__.120 Stewardship Plans – Enforcement and Penalties.

23 11.__.130 Stewardship Plans – Regulations, Guidelines, and Reports.

24 11.__.140 Plan Review and Annual Operation Fees.

- 1 11.___.150 Information Required at Point of Sale.
- 2 11.___.160 Stewardship Plans – Promotion, Outreach and Education.
- 3 11.___.170 Undertaking for the General Welfare.
- 4 11.___.180 Compliance With Federal, State, and Local Laws.
- 5 11.___.190 Severability.

6

7 **11.___.010 TITLE.**

8 This Chapter may be cited as the Pharmaceuticals and Sharps Collection and Disposal
9 Stewardship Ordinance.

10

11 **11.___.015 PURPOSE.**

12 The purpose of this Chapter is to establish a Pharmaceutical and Sharps Stewardship
13 Program that: (1) allows for the safe, convenient and sustainable collection and disposal of
14 unwanted Drugs and Sharps by County residents, and (2) protects, maintains, restores and/or
15 enhances the environment and its natural resources. Said Stewardship Program shall be
16 designed, operated and funded by the Pharmaceutical and Sharps industries with oversight
17 by the County Department of Public Health.

18 This Chapter is intended to supplement the provisions of federal and state law by
19 prescribing higher standards of sanitation, health and safety where not preempted by federal
20 or state law. Whenever any technical words or phrases are not defined herein, but are
21 defined under federal or state law, such definitions are incorporated into this Chapter and
22 shall be deemed to apply as though set forth herein in full.

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24 **11.___.020 DEFINITIONS.**

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1 For purposes of this Chapter, the following definitions shall apply:

2 "Collection Site" shall mean a location where one or more receptacles are provided
3 pursuant to a Stewardship Plan for County residents to safely and securely deposit Unwanted
4 Covered Drugs and/or Unwanted Sharps.

5 "Collector" shall mean a Person who hosts one or more receptacles for the collection of
6 Unwanted Covered Drugs and/or Unwanted Sharps pursuant to this Chapter.

7 "Contact Information" shall mean a business phone number, facsimile phone number,
8 mailing address, and electronic mail address.

9 "Controlled Substances" for purposes of this Section shall mean any substance listed
10 under the California Health and Safety Code Sections 11053 through 11058 or Title 21 of the
11 United States Code Sections 812 and 813 or any successor legislation.

12 "County" shall mean the County of Los Angeles.

13 "Covered Drug" shall mean a Drug in any form, including a controlled substance, that is
14 sold, offered for sale to, or otherwise distributed for use by, one or more consumers in the
15 Service Area, including prescription, nonprescription, brand name, and generic. "Covered
16 Drug" shall include controlled substances and, notwithstanding the previous sentence, shall
17 not include : (1) vitamins or supplements; (2) herbal-based remedies and homeopathic drugs,
18 products, or remedies; (3) cosmetics, shampoos, sunscreens, toothpaste, lip balm,
19 antiperspirants, or other personal care products that are regulated as both cosmetics and
20 nonprescription drugs under the federal Food, Drug, and Cosmetic Act or any successor
21 legislation; (4) Drugs for which Responsible Stewards provide a pharmaceutical product
22 stewardship or take-back program as part of a federal Food and Drug Administration-
23 managed risk evaluation and mitigation strategy (Title 21 U.S.C. Sec. 355-1); and (5) Drugs
24 that are biological products as defined by 21 C.F.R. 600.3(h) as it exists on the effective date
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1 of this Chapter if the Responsible Steward already provides a pharmaceutical product
2 stewardship or take-back program.

3 “Department” shall mean the Department of Public Health.

4 “Director” shall mean the Director of the Department of Public Health or his or her
5 designee.

6 “Drug” shall mean: (1) any article recognized in the official United States
7 Pharmacopoeia - National Formulary, the official homeopathic pharmacopoeia of the United
8 States or any supplement of the formulary or those pharmacopoeias as published by the U.S.
9 Pharmacopoeial Convention and the Homeopathic Pharmacopoeia Convention of the United
10 States; (2) any substance intended for use in the diagnosis, cure, mitigation, treatment, or
11 prevention of disease in humans or other animals; (3) any substance, other than food,
12 intended to affect the structure or any function of the body of humans or other animals; or (4)
13 any substance intended for use as a component of any substance specified in (1), (2), or (3)
14 of this definition, but not a device or a component, part or accessory of a device.

15 “FDA” shall mean the United States Food and Drug Administration.

16 “Hazardous Waste Disposal Facility” shall have the meaning set forth by the United
17 States Environmental Protection Agency under Title 40 Code of Federal Regulations, Parts
18 264 and 265, or any successor legislation.

19 “Manufacture” shall mean the production, preparation, propagation, compounding or
20 processing of a Drug or other substance or device, but shall not include the preparation,
21 compounding, packaging, or labeling of such a Drug, substance or device by a practitioner
22 incidental to the administration or dispensing of a Drug, substance or device in the course of
23 his or her professional practice.

1 “Mail-Back Services” shall mean a collection method for Unwanted Covered Drugs
2 and/or Unwanted Sharps from County residents utilizing Mailers for shipment to a Person that
3 will dispose of them in accordance with the Stewardship Plan.

4 “Mailer” shall mean a prepaid, preaddressed, tamper-resistant envelope or container
5 used for mailing Unwanted Covered Drugs and/or Unwanted Sharps. Any Mailer used for
6 Unwanted Sharps must be FDA-compliant.

7 “Nonprescription Drug” shall mean a Drug that may be lawfully sold without a
8 prescription.

9 “Participating City” shall mean an incorporated city within the County that adopts the
10 requirements of this Chapter into its respective municipal code.

11 “Person” shall mean a human being, firm, sole proprietorship, corporation, limited
12 liability company, general partnership, limited partnership, limited liability partnership,
13 association, cooperative, or other entity of any kind or nature.

14 “Pharmaceutical” shall have the same meaning as Drug.

15 “Pharmacy” shall mean an area, place, or premises licensed by the state of California
16 Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions
17 are dispensed.

18 “Potential Authorized Collector” shall mean any entity that is registered, or that may
19 apply to register, with the U.S. Drug Enforcement Administration (DEA) for the collection of
20 Drugs, such as a manufacturer, distributor, reverse distributor, narcotic treatment program,
21 retail Pharmacy, or a hospital/clinic with an on-site Pharmacy.

22 “Repackager” shall mean a Person who owns or operates an establishment that
23 repacks and/or relabels a product or package for further sale or distribution.

24 “Responsible Steward” shall mean:
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1 (a) The Person who Manufactures or causes to be Manufactured a Covered
2 Drug or Sharps; or

3 (b) If the Person described in (a) is beyond the County's jurisdiction, the first
4 Person who repackages or distributes the Covered Drug or Sharps in or into the
5 County, including but not limited to a Wholesaler or Repackager; or

6 (c) if the Persons described in (a) and (b) are beyond the County's jurisdiction,
7 the first Person who sells or offers for sale the Covered Drug or Sharps in or into the
8 County.

9 "Service Area" shall mean the unincorporated County and all Participating Cities.

10 "Sharp" shall mean a needle, safety engineered needle, lancet or other similar
11 instrument that is designed to puncture the skin of individuals or animals for medical purposes
12 and that is sold, offered for sale, or otherwise distributed for use by one or more consumers in
13 the County and may include anything affixed to the instrument, such as a syringe.

14 "Stewardship Organization" shall mean an organization designated by a Responsible
15 Steward or group of Responsible Stewards to act as its agent to develop and implement a
16 Stewardship Plan.

17 "Stewardship Plan" or "Plan" shall mean a plan approved by the Director for the
18 collection, transportation, and disposal of Unwanted Covered Drugs and/or Unwanted Sharps
19 pursuant to this Chapter that is financed, developed, and implemented by a Responsible
20 Steward operating individually, jointly with other Responsible Stewards, or through a
21 Stewardship Organization.

22 "Stewardship Program" or "Program" shall mean the County program described in this
23 Chapter.

1 “Unincorporated Community” shall mean a community located within the
2 unincorporated area of the County, as identified by the County’s Chief Executive Officer on its
3 official website.

4 “Unwanted Covered Drug” shall mean any Covered Drug that the consumer wishes to
5 discard. This shall exclude Covered Drugs disposed of by commercial and institutional
6 sources including, but not limited to, hospitals, clinics, and Pharmacies.

7 “Unwanted Sharps” shall mean any Sharp or Sharps that the consumer wishes to
8 discard. This shall exclude Sharps disposed of by commercial and institutional sources
9 including, but not limited to, hospitals, clinics, and Pharmacies.

10 “Wholesaler” shall mean a Person who purchases Covered Drugs and/or Sharps for
11 resale and distribution to Persons other than consumers.

12
13 **11.030 STEWARDSHIP PLANS – PARTICIPATION.**

14 (a) Each Responsible Steward must notify the Director in writing of the Responsible
15 Steward’s intent to operate or participate in a Stewardship Plan for the collection,
16 transportation, and disposal of the Covered Drug or Sharps, respectively, within six months of
17 the effective date of this Chapter or six months after the Covered Drug or Sharps are first sold
18 into or offered for sale in the County, whichever is later.

19 (b) Each Responsible Steward shall participate in such a Stewardship Plan approved
20 by the Director either by: (1) operating, individually or jointly with other Responsible Stewards;
21 or (2) entering into an agreement with a Stewardship Organization to operate, on the
22 Responsible Steward’s behalf.

23 (c) Each Stewardship Plan must be approved by the Director before any collection of
24 Unwanted Covered Drugs and/or Unwanted Sharps may commence thereunder. Proposed
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1 changes to an approved Plan shall be subject to the requirements set forth in Section
2 11.____.110.

3 (d) Each Responsible Steward operating individually, jointly with other Responsible
4 Stewards, or through a Stewardship Organization shall:

5 (1) Within six months of the effective date of this Chapter or six months after the
6 Covered Drug or Sharps are first sold or offered for sale in or into the County, whichever is
7 later, identify to the Director in writing an individual authorized to be the official point of contact
8 for the Stewardship Plan and the individual's Contact Information. Said Contact Information
9 shall be kept current at all times. Director shall be notified of any change in such Contact
10 Information within ten (10) business days;

11 (2) Within six months of the effective date of this Chapter or six months after the
12 Covered Drug or Sharps are first sold or offered for sale in the County, whichever is later, and
13 annually thereafter, notify the following Persons of the opportunity to participate in the
14 Stewardship Plan by serving as Collectors, and provide the Director with copies of all such
15 notifications:

16 (A) All retail Pharmacies, hospitals/clinics with on-site Pharmacies, and
17 other Potential Authorized Collectors;

18 (B) Persons other than Potential Authorized Collectors, such as retail
19 establishments, that could potentially host Collection Sites for Sharps; and

20 (C) All law enforcement agencies in the County.

21 (3) Within nine months of the effective date of this Chapter or nine months after
22 the Covered Drug or Sharps are first sold or offered for sale in or into the County, whichever is
23 later, submit a proposed Stewardship Plan as described in Section 11.____.040 to the Director
24 for review;

1 (4) Within three months of the Director's approval of the Stewardship Plan, the
2 Stewardship Plan shall be implemented in accordance with this Chapter;

3 (5) At least every three years after the Stewardship Plan commences
4 operations, submit an updated Stewardship Plan to the Director explaining any substantive
5 changes to the Stewardship Plan. The updated Stewardship Plan shall be accompanied by
6 the plan review fee in accordance with Section 11.____.140 of this Chapter. The Director shall
7 review updated Stewardship Plans using the process described in Section 11.____.100.

8 (e) A Responsible Steward, operating individually, jointly with other Responsible
9 Stewards, or through a Stewardship Organization, may enter into agreements with other
10 Stewardship Organizations, service providers, or other Persons as needed to carry out its
11 Stewardship Plan in whole or in part.

12 (f) Should the Responsible Steward undergo any change in ownership or control, it
13 must notify the Director within 30 days of such change, and should ownership or control be
14 transferred to a company not conducting business in the County, the Responsible Steward
15 shall provide the name and Contact Information of the first Person who causes the Covered
16 Drug or Sharps to be brought in or into the County for repackaging, distribution, or sale.

17 (g) Each Responsible Steward, operating individually, jointly with other Responsible
18 Stewards, or through a Stewardship Organization, shall commence within thirty (30) calendar
19 days good faith negotiations with any Responsible Steward expressing an interest to
20 participate in its Stewardship Plan. For every Responsible Steward not accepted as a
21 participant in the Plan, the Responsible Steward, group of Responsible Stewards, or
22 Stewardship Organization rejecting the Responsible Steward expressing an interest to
23 participate shall notify the Director in writing within thirty (30) calendar days of the rejection
24 and set forth the reasons for such decision.

1 (h) Any Person who is not a Responsible Steward, such as a Person providing
2 Covered Drugs or Sharps free of charge, may choose to participate in the Program. Such
3 Person may operate individually, jointly with a Responsible Steward or group of Responsible
4 Stewards, or through a Stewardship Organization. Any Responsible Steward, group of
5 Responsible Stewards, or Stewardship Organization approached by such Person for potential
6 collaboration must in good faith consider allowing such Person to participate in its
7 Stewardship Plan. Should such Person participate in the Program, such Person shall be
8 subject to the same requirements under this Chapter as any Responsible Steward, group of
9 Responsible Stewards, or Stewardship Organization. If such Person no longer wishes to
10 participate in the Program, such Person shall notify the Director of same within thirty (30)
11 calendar days.

12 (i) After the first full year of implementation of a Stewardship Plan, a Responsible
13 Steward may notify the Director in writing of its intent to submit a new Stewardship Plan.
14 Within three months of such notification, the Responsible Steward, operating individually,
15 jointly with other Responsible Stewards, or through a Stewardship Organization, shall submit
16 a proposed Stewardship Plan as described under Section 11.____.040 to the Director for review.
17 The new Stewardship Plan shall be accompanied by the plan review fee in accordance with
18 Section 11.____.140 of this Chapter. The Director shall review new Stewardship Plans using
19 the process described in Section 11.____.100.

20 (j) Should a Responsible Steward, operating individually, jointly with other Responsible
21 Stewards, or through a Stewardship Organization, become aware of any Covered Drug or
22 Sharps being sold or offered for sale in or into the County whose Responsible Steward is
23 neither operating nor participating in a Stewardship Plan, the Responsible Steward becoming
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1 aware of this shall notify the Director of same and the basis for such belief within thirty (30)
2 calendar days.

3 (k) The Director may, on a case-by-case basis, approve in writing requests for time
4 extensions related to submission dates and deadlines in this Section 11.____.030.

5 (l) The Director may audit the records of a Responsible Steward, group of Responsible
6 Stewards, or Stewardship Organization related to a Stewardship Plan or request that the
7 Responsible Steward, group of Responsible Stewards, or Stewardship Organization arrange
8 for the Director to inspect at reasonable times the facilities, vehicles, and equipment used in
9 carrying out the Stewardship Plan.

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11 **11.____.040 STEWARDSHIP PLANS – COMPONENTS.**

12 Each Stewardship Plan, which must be submitted and reviewed according to Section
13 11.____.110, shall include:

14 (a) The name of each Responsible Steward participating in the Stewardship Plan; the
15 name of each Covered Drug and type of Sharp the Responsible Steward either Manufactures
16 or purchases for repackaging, distribution, sale or offer of sale; and the name and Contact
17 Information of an individual authorized to be the official point of contact for each Responsible
18 Steward and to whom the Director may direct all inquiries regarding the Responsible
19 Steward’s compliance with the requirements of this Chapter;

20 (b) A description of the proposed collection system designed to provide safe,
21 convenient, and ongoing collection services for Unwanted Covered Drugs and Unwanted
22 Sharps from County residents within the Service Area in compliance with the requirements set
23 forth in Section 11.____.050. The description shall include but not be limited to a list of all
24 collection methods and participating Collectors; a list of addresses for the Collection Sites; a
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1 description of how any periodic collection events will be scheduled and where they will be
2 located; and a description of how any Mail-Back Services will be provided to County residents
3 in the Service Area, including a physical sample of the Mailers to be used. The description of
4 the collection services shall include a list of Potential Authorized Collectors, law enforcement
5 agencies, and other Persons contacted by the Responsible Steward pursuant to Section
6 11.___.030, and a list of all who expressed an interest in serving as Collectors in the
7 Stewardship Plan;

8 (c) A description of the proposed handling and disposal system, including the name
9 and Contact Information for each Collector, each Person retained to transport the collected
10 items, each Hazardous Waste Disposal Facility to be used by the Stewardship Plan in
11 accordance with Sections 11.___.050 and 11.___.060, and any other Person retained to
12 implement any portion of the Stewardship Plan;

13 (d) A description of the policies and procedures to be followed by Persons handling
14 Unwanted Covered Drugs and Unwanted Sharps collected under the Stewardship Plan,
15 including a description of how each Collector, each Person retained to transport the collected
16 items, Hazardous Waste Disposal Facilities, and any other Person retained to implement any
17 portion of the Plan will ensure that the collected items are safely and securely tracked from
18 collection through final disposal, and how the Responsible Stewards participating in the
19 Stewardship Plan will ensure that all Persons participating in, operating, and otherwise
20 implementing the Stewardship Plan will comply with all applicable federal, state, and local
21 laws and regulations, including but not limited to those of the United States Drug Enforcement
22 Administration and the State of California Board of Pharmacy;

23 (e) A certification that any patient information appearing on Drug and Sharp packaging
24 will be kept secure and promptly destroyed;

1 (f) A description of the public education and promotion strategy required in Section
2 11.__.160, including but not limited to a copy of instructions, signage, and promotional
3 materials for residents, as well as instructions and signage, as may be needed, for Collectors,
4 Persons retained to transport collected items, Hazardous Waste Disposal Facilities, and all
5 other Persons implementing any portion of the Plan;

6 (g) Proposed short-term and long-term plans for frequency of collection from Collection
7 Sites, public education, and promotion of the Plan; and

8 (h) A description of how the Stewardship Plan will consider: (1) use of existing
9 providers of waste pharmaceutical services; (2) separating Covered Drugs and Sharps from
10 packaging to the extent possible to reduce transportation and disposal costs; and (3) recycling
11 of Drug and Sharp packaging to the extent feasible.

12
13 **11.__.050 STEWARDSHIP PLANS – COLLECTION OF COVERED DRUGS AND SHARPS.**

14 (a) This Chapter does not require any Person to serve as a Collector in a Stewardship
15 Plan. A Person may offer to serve as a Collector with or without compensation by a
16 Responsible Steward, group of Responsible Stewards, or Stewardship Organization.
17 Responsible Stewards are encouraged to host Collection Sites where feasible.

18 (b) The collection system for each Stewardship Plan shall:

19 (1) Provide ongoing, reasonably convenient and equitable access for all County
20 residents in the Service Area regardless of the racial, cultural, or socioeconomic
21 composition of the neighborhoods within which the Collection Sites are located. At a
22 minimum, the following requirements shall be met:

23 A. Population Density: In each Unincorporated Community and in each
24 Participating City with at least one Potential Authorized Collector, each
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1 Stewardship Plan shall provide at least one Collection Site for Unwanted
2 Covered Drugs, at least one Collection Site for Unwanted Sharps, and for every
3 30,000 County residents at least one additional Collection Site for Unwanted
4 Covered Drugs and at least one additional Collection Site for Unwanted Sharps.

5 B. Travel Distance: Collection Sites shall be geographically distributed
6 so as to ensure that every resident within the Service Area is within 2.5 miles of
7 a Collection Site for Unwanted Covered Drugs and a Collection Site for
8 Unwanted Sharps to the greatest extent feasible; and

9 C. Sites per Supervisorial District: In no event shall there be fewer than
10 10 Collection Sites for Unwanted Covered Drugs or fewer than 10 Collection
11 Sites for Unwanted Sharps in each County Supervisorial District;

12 (2) In areas where the minimum requirements set forth in subsection (b)(1) are
13 not met, the Stewardship Plan shall set forth the reasons for such failure and provide
14 for monthly collection events and/or Mailers to be distributed to consumers in those
15 areas;

16 (3) Be safe and secure, including requiring the prompt destruction of patient
17 information on any and all packaging;

18 (4) Include a mechanism whereby Responsible Stewards of Sharps
19 participating in the Plan provide for distribution of FDA-compliant Sharps containers
20 designed for the safe handling of Sharps to the consumer free of charge, preferably at
21 the point of sale of the injectable Drug or at the time the consumer otherwise receives
22 the Sharps for usage;

1 (5) Provide FDA-compliant Sharps collection receptacles to any hosts of
2 Collection Sites for Sharps. A Sharp may be refused for collection if it is not placed
3 within a FDA-compliant Sharps container designed for the safe handling of Sharps;

4 (6) Commence good faith negotiations with any Person expressing an interest
5 to serve as a Collector within 30 calendar days of the Person's expression of such
6 interest. For every Person not accepted as a Collector, the Responsible Steward,
7 group of Responsible Stewards, or Stewardship Organization shall submit a written
8 explanation to the Director within 30 calendar days of the rejection setting forth the
9 reasons for such decision; and

10 (7) Provide Mailers and Mail-Back Services, free of charge, to residents in the
11 Service Area upon request through the Stewardship Plan's 24-hour, toll-free phone
12 number and website. Assistance through the toll-free phone number and website shall
13 be in English, Spanish, and other languages as determined by the Department.

14 (c) Collection Sites for Unwanted Covered Drugs shall accept all Covered Drugs and
15 Collection Sites for Unwanted Sharps shall accept all Sharps. All Collection Sites shall be
16 accessible by County residents at least during the hours that the Collector is normally open for
17 business to the public. Collection Sites shall be emptied and otherwise serviced as often as
18 necessary to avoid creating hazardous conditions, including reaching capacity. Collection
19 Sites shall utilize secure collection receptacles in compliance with all applicable federal, state,
20 and local laws, including but not limited to requirements of the DEA and the State of California
21 Board of Pharmacy.

22 (d) Each Responsible Steward, operating individually, jointly with other Responsible
23 Stewards, or through a Stewardship Organization, shall ensure that all Collection Sites
24 prominently display a 24-hour, toll-free phone number and website for the Stewardship Plan.
25

1 Said toll-free phone number and website shall be a means by which any Person can provide
2 feedback on collection activities, including but not limited to the need to empty the receptacles
3 more frequently or reporting a hazardous condition observed at or near the Collection Sites.
4 Each Stewardship Plan shall provide for the immediate abatement of any hazardous condition
5 arising from or related to operations performed under the Stewardship Plan and shall notify
6 the Director within 24 hours of notice of same.

7
8 **11.060 STEWARDSHIP PLANS – DISPOSAL OF COVERED DRUGS AND SHARPS.**

9 (a) Covered Drugs collected under a Stewardship Plan must be disposed of at a
10 permitted Hazardous Waste Disposal Facility.

11 (b) Sharps collected under a Stewardship Plan must be disposed of in accordance
12 with California Health and Safety Code Section 118286 or any successor legislation.

13 (c) The Director may grant approval for a Stewardship Plan to dispose of some or all
14 collected Covered Drugs at a permitted large municipal waste combustor, as defined by the
15 United States Environmental Protection Agency under Title 40 Code of Federal Regulations,
16 Parts 60 and 62, or any successor legislation if the Director deems the use of a Hazardous
17 Waste Disposal Facility described under subsection (a) to be infeasible for the Stewardship
18 Plan based on cost, logistics, or other considerations.

19 (d) A Stewardship Plan may petition the Director for approval to use final disposal
20 technologies that provide superior environmental and human health protection than provided
21 by the disposal technologies in subsections (a) through (c), or equivalent protection at lesser
22 cost. The proposed technology must provide equivalent or superior protection in each of the
23 following areas: (1) monitoring of any emissions or waste; (2) worker health and safety; (3)
24 reduction or elimination of air, water or land emissions contributing to persistent,

1 bioaccumulative, and toxic pollution; and (4) overall impact on the environment and human
2 health.

3
4 **11.__.070 STEWARDSHIP PLANS – ADMINISTRATIVE AND OPERATIONAL COSTS.**

5 (a) Each Responsible Steward, group of Responsible Stewards, or Stewardship
6 Organization participating in a Stewardship Plan shall prepare and implement its Stewardship
7 Plan as required by this ordinance at its own cost and expense.

8 (b) No Responsible Steward, group of Responsible Stewards, Stewardship
9 Organization, or any other Person may charge a point-of-sale fee to consumers to recoup the
10 costs of any Stewardship Plan, nor may they charge a specific point-of-sale collection fee at
11 the time that Covered Drugs and/or Sharps are collected.

12 (c) Responsible Stewards are not required to pay for costs of staff time at Collection
13 Sites provided by Collectors volunteering to participate in a Stewardship Plan.

14
15 **11.__.080 STEWARDSHIP PLANS – REPORTING REQUIREMENTS.**

16 (a) Within six months after the end of the first 12-month period of operation, and
17 annually thereafter, each Responsible Steward, group of Responsible Stewards, and
18 Stewardship Organization shall submit a report to the Director on behalf of participating
19 Responsible Stewards describing their plan’s activities during the previous reporting period.

20 The report must include:

21 (1) A list of Responsible Stewards participating in the Stewardship Plan;

22 (2) The amount, by weight, of Covered Drugs and the amount, by weight, of
23 Sharps collected, including the amount by weight from each collection method used;

24 (3) A list of Collection Sites;

1 (4) The number of Mailers provided to County residents and the method and
2 location of distribution;

3 (5) The number of Sharps containers provided to County residents and the
4 method and location of distribution;

5 (6) The dates and locations of collection events held;

6 (7) The transporters used and the disposal facility or facilities used for all
7 Covered Drugs and Sharps;

8 (8) Whether any safety or security problems occurred during collection,
9 transportation or disposal of Unwanted Covered Drugs and Unwanted Sharps during the
10 reporting period and, if so, what changes have or will be made to policies, procedures or
11 tracking mechanisms to alleviate the problem and to improve safety and security in the future;

12 (9) A description of the public education, outreach and evaluation activities
13 implemented during the reporting period;

14 (10) A description of how collected packaging was recycled to the extent
15 feasible, including the recycling facility or facilities used, and the amount of packaging
16 collected by weight and percent recycled;

17 (11) A summary of the Stewardship Plan's goals, the degree of success in
18 meeting those goals in the past year, and, if any goals have not been met, what effort will be
19 made to achieve the goals in the next year; and

20 (12) The total expenditures of the Stewardship Plan during the reporting period.

21 (13) An Executive Summary.

22 (b) Each Responsible Steward, group of Responsible Stewards, and Stewardship
23 Organization shall provide on a quarterly basis, a list of Responsible Stewards participating in
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1 the Stewardship Plan. Any change in the official point of contact for the Plan must be
2 provided to the Department within 30 days of the change.

3 (c) The Director shall make reports submitted under this Chapter available to the
4 public.

5 (d) For the purposes of this Section 11.____.080, "reporting period" means the period
6 from January 1 through December 31 of the same calendar year, unless otherwise specified
7 by the Responsible Steward, group of Responsible Stewards, and Stewardship Organization
8 to the Director.

9
10 **11.____.090 STEWARDSHIP PLANS – IDENTIFICATION OF RESPONSIBLE STEWARDS**
11 **OF COVERED DRUGS AND SHARPS.**

12 Any Person receiving a letter of inquiry from the Director regarding whether or not it is a
13 Responsible Steward under this Chapter must respond in writing within 60 days. If such
14 Person does not believe it is a Responsible Steward under this Chapter, it must state the
15 basis for such belief. It must also provide a list of all Covered Drugs and Sharps it
16 repackages, distributes, sells, or offers for sale within the County, if any, and identify the name
17 and Contact Information of the Person(s) from whom it acquired said Covered Drugs or
18 Sharps.

19
20 **11.____.100 STEWARDSHIP PLANS – REVIEW OF PROPOSED PLANS.**

21 (a) By nine months after the effective date of this Chapter, each Responsible Steward,
22 group of Responsible Stewards, or Stewardship Organization shall submit its proposed
23 Stewardship Plan to the Director for review, accompanied by the plan review fee in
24 accordance with Section 11.____.140 of this Chapter. The Director may upon request provide
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1 information, suggestions, and technical assistance about the requirements of this Chapter to
2 assist with the development of a proposed Stewardship Plan.

3 (b) The Director shall review the proposed Stewardship Plan and determine whether it
4 meets the requirements of this Chapter.

5 (c) After the review under subsection (b) and within 90 days after receipt of the
6 proposed Stewardship Plan, the Director shall either approve or reject the proposed
7 Stewardship Plan in writing and, if rejected, provide reasons for the rejection.

8 (d) If the Director rejects a proposed Stewardship Plan, a Responsible Steward, group
9 of Responsible Stewards, or Stewardship Organization must submit a revised Stewardship
10 Plan to the Director within 60 days after receiving written notice of the rejection. The Director
11 shall review and approve or reject a revised Stewardship Plan as provided under subsections
12 (b) and (c).

13 (e) If the Director rejects a revised Stewardship Plan, or any subsequently revised
14 plan, the Director may deem the Responsible Steward, group of Responsible Stewards, or
15 Stewardship Organization out of compliance with this Chapter and subject to the enforcement
16 provisions in this Chapter.

17 (f) The Department, at the sole discretion of the Director, may establish a technical
18 advisory committee to assist the Department in reviewing Stewardship Plans or otherwise
19 assisting in the implementation of this ordinance.

20 (g) The Director shall make all proposed and approved Stewardship Plans submitted
21 under this Chapter available to the public for review and comment.

22
23 **11.110 STEWARDSHIP PLANS – PRIOR APPROVAL FOR CHANGE.**

1 (a) Proposed changes to an approved Stewardship Plan that substantively alter plan
2 operations, including, but not limited to, changes to participating Responsible Stewards,
3 Collectors, collection methods, Hazardous Waste Disposal Facilities, how to achieve the
4 service convenience goal, policies and procedures for handling Unwanted Covered Drugs and
5 Unwanted Sharps, or education and promotion methods, must be approved in writing by the
6 Director before the changes are implemented.

7 (b) A Responsible Steward, group of Responsible Stewards, or Stewardship
8 Organization shall submit to the Director any proposed change to a Stewardship Plan in
9 writing at least 30 days before the change is scheduled to take effect. Any such submittal
10 shall be accompanied by the review fee in accordance with Section 11.____.140 of this Chapter.

11 (c) A Responsible Steward, group of Responsible Stewards, or Stewardship
12 Organization shall notify the Director at least 15 days before implementing any changes to
13 Collection Site locations, methods for scheduling and locating periodic collection events, or
14 methods for distributing Mailers, that do not substantively alter achievement of the service
15 convenience goal under Section 11.____.050 of this Chapter, or other changes that do not
16 substantively alter plan operations under subsection (a).

17 (d) A Responsible Steward, group of Responsible Stewards, or Stewardship
18 Organization may request an advance determination from the Director whether a proposed
19 change would be deemed to substantively alter plan operations.

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21 **11.____.120 STEWARDSHIP PLANS – ENFORCEMENT AND PENALTIES.**

22 (a) The Director shall administer the penalty provisions of this Chapter.

23 (b) If the Director determines that any Person has violated any provision of this
24 Chapter or a regulation adopted pursuant to this Chapter, the Director shall send a written
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1 warning, as well as a copy of this Chapter and any regulations adopted pursuant to this
2 Chapter, to the Person or Persons who violated it. The Person or Persons shall have 45 days
3 after the date of mailing of the warning to come into compliance and correct all violations.

4 (c) If the Person or Persons fail to come into compliance or correct all violations, the
5 Director may impose administrative fines for violations of this Chapter or of any regulation
6 adopted pursuant to this Chapter, Los Angeles County Code, Title 1, Chapter 1.25, as
7 amended, is hereby incorporated in its entirety and shall govern the imposition, enforcement,
8 collection, and review of administrative citations issued to enforce this Chapter or any rule or
9 regulation adopted pursuant to this Chapter. Each day shall constitute a separate violation for
10 these purposes.

11 (d) County Counsel, the District Attorney, and any applicable City Attorney may bring a
12 civil action to enjoin violations of or compel compliance with any requirement of this Chapter
13 or any rule or regulation adopted pursuant to this Chapter, as well as for payment of civil
14 penalties and any other appropriate remedy. The court shall award reasonable attorney's
15 fees and costs to County Counsel, the District Attorney, and any applicable City Attorney.

16 (e) Any Person who knowingly and willfully violates the requirements of this Chapter or
17 any rule or regulation adopted pursuant to this Chapter is guilty of a misdemeanor and upon
18 conviction thereof is punishable by a fine of not less than fifty dollars (\$50) and not more than
19 one thousand (\$1,000) for each day per violation, or by imprisonment for a period not to
20 exceed six months, or by both such fine and imprisonment.

21 (f) Any Person in violation of this Chapter or any rule or regulation adopted pursuant to
22 this Chapter shall be liable to the County for a civil penalty in an amount not to exceed one
23 thousand dollars (\$1,000) per day per violation. Each day in which the violation continues
24 shall constitute a separate violation. Civil penalties shall not be assessed pursuant to this
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1 subsection (f) for the same violations for which the Director assessed an administrative
2 penalty pursuant to subsection (c).

3 (g) In determining the appropriate penalties, the court or the Director shall consider the
4 extent of harm caused by the violation, the nature and persistence of the violation, the
5 frequency of past violations, any action taken to mitigate the violation, and the financial
6 burden to the violator.

7 (h) The Director may exercise reasonable discretion to waive strict compliance with the
8 requirements of this Chapter that apply to Responsible Stewards in order to achieve the
9 objectives of this Chapter.

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11 **11.130 STEWARDSHIP PLANS – REGULATIONS, GUIDELINES, AND REPORTS.**

12 (a) The Director may adopt regulations and guidelines necessary to implement,
13 administer, and enforce this Chapter.

14 (b) The Director may work with each Responsible Steward, group of Responsible
15 Stewards, and Stewardship Organization as needed, but no less than annually, to define
16 goals and performance, including but not limited to collection amounts, education, and
17 promotion for a Stewardship Plan.

18 (c) The Director shall report biennially to the Board of Supervisors concerning the
19 status of all Stewardship Plans and recommendations for changes to this Chapter. The
20 biennial report may also include a summary of available data on indicators and trends of
21 pharmaceutical pollution, abuse, poisonings and overdoses from prescription and
22 nonprescription drugs and a review of comprehensive prevention strategies to reduce risks of
23 drug abuse, overdoses, and preventable poisonings. The first report shall be due two years
24 from the effective date of this Chapter.

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11.__.140 PLAN REVIEW AND ANNUAL OPERATION FEES.

(a) Each Responsible Steward, group of Responsible Stewards, and Stewardship Organization participating in a Stewardship Plan shall pay to the Director plan review fees to be established under subsection (d) for the performance of certain functions as applicable, including but not limited to:

- (1) Review of a proposed Stewardship Plan;
- (2) Review of a revised, proposed Stewardship Plan;
- (3) Review of changes to an approved Stewardship Plan;
- (4) Review of an updated Stewardship Plan at least every three years as required under Section 11.__.030 of this Chapter;
- (5) Review of any petition for approval to use alternative final disposal technologies under Section 11.__.060 of this Chapter; and
- (6) Environmental review of a Stewardship Plan.

(b) In addition to plan review fees, each Responsible Steward, group of Responsible Stewards, and Stewardship Organization shall pay to the Director annual operating fees to be established under subsection (d) of this Section 11.__.140.

(c) A Stewardship Organization may remit the plan review fee on behalf of its participating Responsible Stewards.

(d) As soon as practicable, the Director shall propose to the Board of Supervisors a schedule of fees charged to each Responsible Steward, group of Responsible Stewards, and Stewardship Organization to cover costs of administering and enforcing this Chapter. The Director shall set the fees to recover but not exceed actual and reasonable costs to the County. The Board of Supervisors must approve the schedule of fees after a public hearing

1 for it to become effective. The Auditor-Controller shall confirm that the fees set by the Director
2 do not exceed the actual and reasonable costs to the County.

3
4 **11.__.150 INFORMATION REQUIRED AT POINT OF SALE.**

5 (a) Any Person selling or offering for sale Covered Drugs or Sharps to the public shall
6 post display materials approved by the Director explaining how and where members of the
7 public may safely and lawfully dispose of Unwanted Covered Drugs and Unwanted Sharps at
8 no cost to the consumer. The materials shall be in English, Spanish, and other languages as
9 determined by the Department and shall be legible and easily understandable by the average
10 person. The materials shall be posted on the premises of the Person's place of business in a
11 location visible to the public, if applicable, and adjacent to the area where prescription drugs
12 are dispensed. Mail-order Pharmacies and on-line Pharmacies selling Covered Drugs or
13 Sharps to County residents shall provide such materials with the order.

14 (b) The Director may, in his or her discretion, authorize a business to use alternate
15 means to comply with the requirements of subsection (a). No Person may sell or offer for sale
16 Covered Drugs or Sharps to the public using any alternate means of compliance with this
17 Chapter unless specifically authorized to do so in advance in writing by the Director.

18
19 **11.__.160 STEWARDSHIP PLANS – PROMOTION, OUTREACH AND EDUCATION.**

20 (a) Each Responsible Steward, group of Responsible Stewards, or Stewardship
21 Organization shall develop a system of promotion, outreach, and public education to be
22 included in the Stewardship Plan. Specifically, each Responsible Steward, group of
23 Responsible Stewards, or Stewardship Organization shall:

1 (1) Promote the collection options offered under its Stewardship Plan to
2 residents and the health care community. Promotion shall include outreach and educational
3 materials:

- 4 A. Promoting safe storage of Drugs and Sharps by residents during the
5 treatment period;
- 6 B. Describing where and how to return Unwanted Covered Drugs and
7 Unwanted Sharps under the Stewardship Plan;
- 8 C. Expressly discouraging stockpiling of Unwanted Covered Drugs and
9 Unwanted Sharps; and
- 10 D. Expressly discouraging disposal of said items in the trash or through
11 a plumbing or septic system.

12 These materials must be provided to Pharmacies, retailers of Covered Drugs and
13 Sharps, health care practitioners, health care facilities, veterinary facilities, and other
14 prescribers for their own education as well as for dissemination to residents;

15 (2) Use Plain language and explanatory images so as to be readily
16 understandable by all residents, including individuals with limited English proficiency;

17 (3) Work with Collectors participating in Stewardship Plans to develop clear,
18 standardized instructions, signage and promotional materials for residents on the use of
19 collection receptacles and a readily-recognizable, consistent design of collection receptacles;

20 (4) Establish a 24-hour, toll-free phone number and single website where
21 information can be obtained regarding collection options and current locations of Collection
22 Sites;

23 (5) Within six months of the effective date of this Chapter and biennially
24 thereafter conduct a survey of residents, pharmacists, veterinarians, retailers, and health
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1 professionals who interact with patients on the use of Drugs and Sharps after the first full year
2 of operation of the plans. Survey questions shall include but not be limited to questions
3 designed to: (1) assess the awareness of the County's Stewardship Program, the
4 Stewardship Plans in operation, and the location of all available Collection Sites; (2) assess to
5 what extent Collection Sites and other collection methods are safe, convenient, easy to use,
6 and utilized by residents; and (3) assess knowledge and attitudes about risks of abuse,
7 poisonings and overdoses from prescription and nonprescription Drugs used in the home.
8 Draft survey questions shall be submitted to the Director for review and comment at least 30
9 days prior to initiation of the survey. Results of the survey shall be reported to the Director
10 and made available to the public on the website required in this Section 11.____.060 within 90
11 days following the end of the survey period. Each Responsible Steward, group of
12 Responsible Stewards, and Stewardship Organization shall ensure the privacy of all survey
13 respondents.

14 (b) All surveys, outreach, education, promotion, websites, and toll-free phone numbers
15 required by this Section 11.____.160 shall be in English, Spanish, and other languages as
16 determined by the Department. If more than one Stewardship Plan is approved, then to the
17 extent feasible, all Stewardship Plans shall coordinate with each other and develop a single
18 system of promotion and education, with a single toll-free hotline and website and consistent
19 signage and materials across the County.

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21 **11.____.170 UNDERTAKING FOR THE GENERAL WELFARE.**

22 In adopting and implementing this Chapter, the County is assuming an undertaking
23 only to promote the general welfare. It is not assuming, nor is it imposing on its officers and
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1 employees, an obligation for breach of which it is liable in money damages to any Person who
2 claims that such breach proximately caused injury.

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4 **11.__.180 COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS.**

5 Each Responsible Steward, group of Responsible Stewards, and Stewardship
6 Organization operating under this Chapter must comply with all applicable federal, state, and
7 local laws and regulations.

8 Each Responsible Steward, group of Responsible Stewards, and Stewardship
9 Organization operating under this Chapter shall also ensure that each Collector, each Person
10 retained to transport the collected items, and any other Person implementing any portion of
11 the Stewardship Plan complies with all applicable federal, state and local laws and
12 regulations.

13 This Chapter shall be construed so as not to conflict with applicable federal or State
14 laws, rules or regulations. Nothing in this Chapter shall authorize any agency or department
15 to impose any duties or obligations in conflict with limitations on municipal authority
16 established by State or federal law at the time such agency or department action is taken.
17 The County shall suspend enforcement of this Chapter to the extent that said enforcement
18 would conflict with any preemptive State or federal legislation subsequently adopted. Nothing
19 in this Chapter is intended or shall be construed to protect anticompetitive or collusive
20 conduct, or to modify, impair, or supersede the operation of any of the antitrust or unfair
21 competition laws of the State of California or the United States.

22
23 **11.__.190 SEVERABILITY.**

1 If any of the provisions of this Chapter or the application thereof to any Person or
2 circumstance is held invalid, the remainder of those provisions, including the application of
3 such part or provisions to persons or circumstances other than those to which it is held invalid
4 shall not be affected thereby and shall continue in full force and effect. To this end, the
5 provisions of this Chapter are severable.

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